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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,367	09/18/2001	Alan D. Attie	960296.97478	8344

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,367

Applicant(s)

ATTIE ET AL.

Examiner

Diana B. Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) 4,7,9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,8,11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>0806</u> | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

1. This action is responsive to the amendment filed August 10, 2006. Claims 1, 5, 8, and 11 have been amended, and claim 12 has been added. Claims 4, 7, and 9-10 remain withdrawn. Claims 1, 5, 8, 11, and 12 are now under consideration. Applicants' amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph

3. Claims 1, 5, 8, 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, for reasons set forth in the Office action of April 8, 2004 (which reasons were reiterated in the Office action of February 10, 2006). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

It is noted that Applicants' amendments necessitated the inclusion of new claim 12 in this rejection. Claim 12 is drawn to a method of diagnosing susceptibility to obesity. Such methods are enabled in mice, but lack enablement with regard to other types of individuals (as discussed with regard to claim 11 in the Office action of April 8, 2004), for the reasons of record.

The response traverses the rejection on the grounds that "since applicants' filing date researchers in the field have confirmed through numerous reports that diabetes or

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diabetes susceptibility are associated with (decreased) expression levels of SREBP, cytochrome c oxidase subunit VIIa, and/or stearyl-CoA desaturase,” and that “these reports along with the fact that it is well known that insulin resistance is related to diabetes or progression to diabetes, establish a relationship between decreased expression” of these genes in obese individuals “and the levels of expression of those same genes in diabetic individuals.” The response continues with a more detailed discussion of several references, the majority of which were only publicly available subsequent to the filing of the instant application.

Applicants’ arguments have been thoroughly considered but are not persuasive. First, it is noted that it is the state of the art as of the filing date of an application that is used to determine whether the enablement requirement has been met (see MPEP 2164.05(a)). Thus, the majority of the references newly cited by applicants (specifically, Sewter et al (2002), Yang et al (2004), Ducluzeau et al (5/2001), Choo et al (2006)) cannot be relied upon to establish enablement as of the time the invention was made. None of these references appears to provide evidence of, e.g., data supporting applicants’ claims being disclosed prior to applicants’ effective filing date, and applicants have not, e.g., provided any declaratory evidence that such data was available, or, e.g., that the references cited establish enablement as of applicants’ effective filing date. Accordingly, applicants’ arguments with regard to these references are not persuasive.

With regard to the Yki-Jarvinen reference (1995), while the abstract provided by applicants does include a statement that insulin resistance “clearly increases the risk of developing NIDDM,” the abstract is silent with regard to the genes of the instant claims

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and with regard to, e.g., any kind of correlation or association between gene expression levels in obesity and diabetes, in mice and other subjects, etc. Regarding the Shimomura et al reference (1998), it is noted that applicants acknowledge that the reference "does not teach or suggest the association between SREBP or SCD with diabetes or obesity." While the reference shows a relationship between SREBP and SCD expression levels, such a relationship does not provide evidence that particular expression levels of these genes indicate or are associated with obesity or diabetes, as would be required to enable the claims. Thus, applicants' arguments are not persuasive.

This rejection is maintained.

Claim Rejections - 35 USC § 112, second paragraph

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS' AMENDMENTS:

4. Claims 1, 8, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite over the recitation of the limitation "the non-diabetic individuals" because there is insufficient antecedent basis for the limitation in the claim.

Claim 8 is indefinite over the recitation of the phrase "determining a decreased level of expression...being indicative of susceptibility to diabetes." It is unclear if the claim as amended remains drawn to a method in which diabetes susceptibility is diagnosed, or whether the method steps of the claim now encompass a method in

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which a level of gene expression associated with diabetes is assayed for and determined. Clarification is required.

Claim 11 is indefinite over the recitation of the limitation "being associated with the transition from obese to diabetic" because it is not clear whether this language is intended to in some way modify the "non-diabetic individual" (and if so, how), or whether this language refers back to, e.g., the "expression pattern."

Claim 11 is indefinite because it is unclear how or whether the "non-diabetic individual" of the "comparing step" relates to the "non-obese and non-diabetic individuals" of the "diagnosing step." Accordingly, it is further clear how or whether the "comparing" and "diagnosing" steps relate to one another and to the objective of "diagnosis or prognosis" set forth in the claim preamble.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Diana B. Johannsen
Primary Examiner
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